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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,882	12/27/2001	Dale R. Pfost	P-OD 5078	2031

41552 7590 03/31/2006

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/034,882	PFOST, DALE R.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1-23-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on January 23, 2006 has been entered.

Claims 1-27 are pending and have been examined herein.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to compositions of compounds effective for treating a pathology, said composition comprising at least two compounds (or 3 or 4 or 5 or 6

compounds) that modulate the activity of one or more target compounds associated with a SNP.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention."

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of specifies have been described by their complete structure. In the instant case, no members of the broadly claimed genus of compounds have been defined by their structure. The specification (see Examples 1 and 2) discusses the use of drugs A, B, C, D and E and the response of

patients having a different genotype to these drugs. However, the specification does not disclose the identity of these drugs, which SNPs the drugs are associated with, what pathology the drugs treat, or the genotype of the patients. Accordingly, the specification does not provide an adequate written description of a single composition within the scope of the claimed invention.

It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, specific biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of the compounds.

Accordingly, the written description requirements have not been met for the claimed genus because a representative number of compounds within the claimed genus have not been defined in terms of their structure or other specific identifying characteristics. While the breadth of the claims is not reasonably quantifiable, it is clear that the genus of compounds that may be included by the claims is enormous. The claims allow for compounds "effective for treating a pathology." Thereby, the claims include compounds that treat any of the diverse pathologies, such as diabetes, Alzheimer's Disease, Cancer, Parkinson's Disease, lupus, AIDS, MS, allergies, malnutrition, depression, drug addiction, gingivitis, epilepsy, etc. etc.... The composition may be used to treat a pathology in a human or any other type of animal. The claims include any type of compound that can be "used to effect a physiological change in treating a pathology" (page 5). Thus, the claims include any type of inorganic or organic compound, such as antisense molecules, antibodies, DNA molecules used for gene

therapy, vaccines, enzymes, and receptors. The compounds are defined in terms of modulating the activity of one or more target molecules. The target molecules, may again, be of any structure. As discussed in the specification (page 6), the target molecule "can vary from as large as an association molecules, such as a ribosome or a lipid bilayer, to as small as a small molecule or an ion, such as a hormone, cytokine, cAMP, NO, Ca^{2+}, K^{+}, phosphate, and the like." The compound may modulate the activity of the target compound by any manner. For instance, the specification (page 6) teaches that the compounds may increase or decrease enzyme activity, may increase or decrease gene expression, may increase or decrease protein-protein interaction, may increase or decrease signal transduction, or may increase or decrease transport or translocation across the membrane. The target compound is described as being associated with one or more SNPs. The relationship between the target compound and SNP is not defined. The claims thereby include target compounds that are in any way related, directly or indirectly, specifically or nonspecifically, with a SNP. The SNP may also be from any gene or protein and may be at any location within the gene or protein.

The specification does not disclose a common structural feature linking the claimed genus of compounds. The claims define the compounds in terms of their functional activity, but do not define any of the structural properties of the compounds. While a limited number of specific individual compounds are known in the art which directly modulate the activity of nucleic acids or proteins containing SNPs, the general knowledge in the art concerning therapeutic compounds does not provide any indication of how the structure of one therapeutic compound is representative of other

therapeutic compounds. The structure and function of a given compound that modulates the activity of one SNP does not provide guidance as to the structure and function of other compounds that modulate the activity of the same or other SNPs. Therefore, the description in the prior art of specific therapeutic compounds is not representative of the very large genus of compositions containing two or more compounds that are effective for treating a pathology.

Additionally, the claims include compositions that are effective for treating at least 1%, 25%, 50%, 75% or 90% of patients having the pathology. Yet, the specification does not disclose a common structural feature or specific property that is present in compounds and which ensures the compounds are effective for treating at least 1%, 255, 50%, 75% or 90% of patients having the pathology. The claims further include compounds that are stably effective for at lest 50%, 75%, or 90% of the patients having the pathology. The specification at page 12 defines stably effective as including compounds whose effectiveness does not change over a time scale of 1, 2, 5, 10, 25, 50 or 100 years. However, the specification does not disclose any particular structural feature which ensures the property that the compounds are stably effective for at least 50%, 75%, or 90% of the patients having the pathology.

For these reasons, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the invention as it is broadly claimed and thus the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of

Patent Applications under 35 U.S.C. 112,. 1 Written Description Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions consisting of the specific HIV vaccine set forth in U.S. Patent No. 5,846,546 and the HBV antibody composition set forth in U.S. Patent No. 5,648,077 (it is noted that the specification does not provide support for the disclosure of these compositions; enablement is provided only via the disclosure of the '546 and '077 patents), does not reasonably provide enablement for compositions containing any two or more compounds that are to be used to effectively treat any pathology, wherein the compounds modulate the activity of one or more target compounds associated with any SNP. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

The claims are broadly drawn to compositions of compounds effective for treating a pathology, said composition comprising at least two compounds (or 3 or 4 or 5 or 6 compounds) that modulate the activity of one or more target compounds associated with a SNP. The specification does not adequately teach one of skill in the art how to make and use the claimed genus of compositions without undue experimentation for the following reasons.

The breadth of the claims is significantly large. The claims require 2 or more compounds "effective for treating a pathology." Thereby, the claims include compounds that treat any of the diverse pathologies, such as diabetes, Alzheimer's Disease, Cancer, Parkinson's Disease, lupus, AIDS, MS, allergies, malnutrition, depression, drug addiction, gingivitis, epilepsy, etc. etc.... The composition may be used to treat a pathology in a human or any other type of animal. The claims include any type of compound that can be "used to effect a physiological change in treating a pathology" (page 5). Accordingly, the claims include any type of inorganic or organic compound, such as antisense molecules, antibodies, DNA molecules used for gene therapy, vaccines, enzymes, and receptors. The compounds are defined in terms of modulating the activity of one or more target molecules. The target molecules, may again, be of any structure. As discussed in the specification (page 6), the target molecule "can vary from as large as an association molecules, such as a ribosome or a lipid bilayer, to as small as a small molecule or an ion, such as a hormone, cytokine, cAMP, NO, Ca^{2+}, K^{+}, phosphate, and the like." The compound may modulate the activity of the target compound by any manner. For instance, the specification (page 6) teaches that

the compounds may increase or decrease enzyme activity, may increase or decrease gene expression, may increase or decrease protein-protein interaction, may increase or decrease signal transduction, or may increase or decrease transport or translocation across the membrane. The target compound is described as being associated with one or more SNPs. The relationship between the target compound and SNP is not defined. The claims thereby include target compounds that are in any way related, directly or indirectly, specifically or nonspecifically, with a SNP. The SNP may also be from any gene or protein and may be at any location within the gene or protein. Additionally, the claims include compositions that are effective for treating at least 1%, 25%, 50%, 75% or 90% of patients having the pathology. Yet, the specification does not disclose a common structural feature or specific property that is present in compounds and which ensures the compounds are effective for treating at least 1%, 255, 50%, 75% or 90% of patients having the pathology.

The claims further include compounds that are stably effective for at lest 50%, 75%, or 90% of the patients having the pathology. The specification at page 12 defines stably effective as including compounds whose effectiveness does not change over a time scale of 1, 2, 5, 10, 25, 50 or 100 years. However, the specification does not define any particular structural feature which ensures the property that the compounds are stably effective for at lest 50%, 75%, or 90% of the patients having the pathology.

Accordingly, the claims encompass a phenomenally large genus of compounds that are not defined in terms of any specific structural property. Yet, the specification does not provide a single example of a specific compound that falls within the scope of

the claims. The specification (see Examples 1 and 2) discusses the use of drugs A, B, C, D and E and the response of patients having a different genotype to these drugs. However, the specification does not disclose the identity of these drugs, which SNPs the drugs are associated with, what pathology the drugs treat, or the genotype of the patients. Rather, the specification provides a general description of a research project which one might undertake in order to try to identify compositions which fall within the scope of the claims. For example, the specification (page 10) states that methods for identifying SNPs are known in the art. It is also stated that methods are known in the art for analyzing a SNP in order to determine if it is associated with a pathology (page 11). Once a SNP associated with a disease has been identified, one should then screen compounds, in vitro or in vivo, in order to try to identify compounds that may be effective at modulating the activity of a target molecule (pages 14 and 18). The specification teaches that compounds should be selected which, when used in combination, remain effective and do not result in a toxic response.

Clearly, the described research project provides only an invitation to experiment. While methods for analyzing SNPs and therapeutic compounds may be known in the art, providing methods of searching for compounds is not equivalent to providing specific compounds that can be used to treat specific pathologies by modulating the activity of specific target molecules correlated with specific SNPs. Further, while the prior art teaches compounds that modulate the activity of a SNP, such limited teachings directed to specific SNPs associated with specific diseases are not sufficient to support the enablement of the broadly claimed invention of any combination of compounds that

modulate in any manner any SNP present in any gene and associated with any pathology. The experimentation required to identify the compounds present in the claimed compositions is extensive and highly unpredictable and would not be considered by the artisan to be routine. The novel aspect of the claims is the combination of compounds that modulate the activity of a SNP associated with a pathology. The novel aspects of the invention are not the process steps of sequencing to identify a SNP, performing linkage and associated studies to identify SNPs associated with a pathology, or performing general screening methods to identify a compound that modulates the activity of a SNP since these general methodologies are well known in the art.

The art of identifying therapeutic compounds that modulate the activity of a molecule associated with a SNP is highly unpredictable. There is no common structural feature which links therapeutic compounds and which would allow one to ascertain a priori whether a compound will modulate the activity, expression etc of a target molecule that is directly or indirectly associated with a SNP. Given the lack of a specific structure-function relationship between SNPs and the occurrence of a pathology, the lack of a specific structure-function relationship between therapeutic compounds and the ability to modulate target molecules and the lack of a specific structure-function relationship between therapeutic compounds and the ability to treat a pathology, one can only identify SNPs, target molecules and therapeutic compounds through extensive experimentation. Additionally, the specification does not provide any specific guidance as to how to identify compounds that have these attributes when used in combination.

Combinations of compounds can only be identified through random, trial-by-error experimentation. The specification emphasizes the unpredictability of identifying compounds that can be used in combination to effectively treat a pathology. The specification points out that each compound will may have a different effect, such that the effect of one compound may negate the effect a second compound. It is also well known and accepted in the art that compounds may interfere with one another and may in combination cause toxic side-effects. The specification does not provide any guidance as to how to determine a priori which combinations of two, three, four, five, six or more compounds can be used together to effectively treat a pathology. Such information can be obtained only through experimentation.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the specification does not disclose a single composition within the presently claimed genus of compositions. Further, the

specification does not provide the novel aspects of the invention. Rather, the novel aspects of the invention can only be supplied through extensive experimentation. In view of the high level of unpredictability in the art and the lack of specific guidance and working examples provided in the specification, undue experimentation would be required to practice the broadly claimed invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-27 are indefinite over the recitation of "target molecule associated with one or more Single Nucleotide Polymorphisms (SNPs)." The specification states that a "target molecule that is 'associated with' or 'correlated with' a particular genetic variation, preferably a particular SNP, is a molecule that can be functionally distinguished in its structure, activity, concentration, compartmentalization, secretion, and the like, as a result of such genetic variation." However, this teaching does not provide a clear and complete definition for what is intended to be encompassed by target molecules associated with SNPs. It is unclear as to whether the target molecule contains a SNP (e.g., a nucleic acid or protein that contains a SNP) or if the target molecule is in some other way associated with a SNP (e.g., the target molecule itself does not contain a SNP but other members of this class of compounds contains a SNP, or the target molecule is a part of a cycle / cascade involving numerous other

compounds in which one of the other compounds contains a SNP or alters the activity or expression of a SNP or creates the formation of a SNP). Accordingly, it is unclear as to what is intended to be the relationship between the target compound and the SNP.

B. Claim 7 is indefinite over the recitation of "corresponding" because this is not an art recognized term to describe the relationship between a target molecule and a SNP and there is no clear definition provided in the specification for this term. It is not clear as to what is intended to be the relationship between the target molecule and the SNP and it is not clear as to whether "the position" constitutes the location of the polymorphism in a nucleic acid or protein or if the position defines some other unstated relationship between the polymorphism and the target molecule.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-27 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Hurwitz et al (U.S. Patent No. 5,846,546).

Hurwitz discloses HIV vaccines that modulate the activity of target molecules containing SNPs by inducing humoral or cellular immune responses against the target molecule. The vaccines (see, for example, column 2) preferably contain about 10 to 100 recombinant viruses each expressing a different HIV env protein variant (EPV). Each EPV contains a point mutation present in a different strain of HIV (see Table 1). These point mutations are considered to be equivalent to SNPs. Note that page 8 of the present specification defines a SNP as "a genetic variation at a specific site in the genome of an organism, where the nucleotide identity at the site varies between genomic allelic members of a population of organisms." The vaccine is a composition comprising a combination of at least 2 compounds that indirectly modulate the activity of a target protein comprising a SNP. The vaccines are considered to be effective or stably effective for at least 90% of patients having the pathology (i.e., current infection with HIV or susceptibility to infection with HIV; column 29). It is noted that the specification broadly describes what is intended to be encompassed by effective and stably effective. Thereby, "effective" and "stably effective" are considered to encompass any degree of response over any period of time. With respect to claim 7, the claim encompasses any form of indirect interaction between the compound and the target molecule. The ability of the compounds in the vaccine to stimulate antibody production or cellular immunity against HIV antigens thereby constitutes modulation of a target molecule associated with a SNP.

6. Claims 1-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ostberg et al (U.S. Patent No. 5,648,077).

Ostberg discloses a composition comprising antibodies against HBV wherein said composition is effective for treating humans infected with Hepatitis B virus (column 2). The compositions preferably contain a cocktail of antibodies that bind with different variant genes of different HBV strains. The antibodies are encoded by DNA sequences having any of the CDR1, CDR2, or CDR3 regions set forth in Tables 8-1, 8-2, 8-3, and 8-4 and any of the V light chains set forth in Tables 9-1, 9-2, 9-3 and 9-4. Such compositions would thereby comprise at least 6 antibodies. Preferably the compositions comprise at least the antibodies PE1-1, ZM1-1, ZM1-2, MD3-4 and L03-3 (see, for example, columns 3-4). Each antibody binds to a HBV protein having a point mutation present in a different strain of HBV (see, for example, column 3-4, especially lines 5-48 of col. 3). These point mutations are considered to be equivalent to SNPs. Note that page 8 of the present specification defines a SNP as "a genetic variation at a specific site in the genome of an organism, where the nucleotide identity at the site varies between genomic allelic members of a population of organisms." The compositions containing mixtures of HBV antibodies are considered to be effective or stably effective for at least 90% of patients having the pathology (i.e., current infection with HIV or susceptibility to infection with HIV; column 29). It is noted that the specification broadly describes what is intended to be encompassed by effective and stably effective. Thereby, "effective" and "stably effective" are considered to encompass any degree of response over any period of time. With respect to claim 7, the claim encompasses any form of indirect interaction between the compound and the target molecule. The ability of the compositions to bind to HBV proteins having mutations and to neutralize viral

particles is considered to constitute modulation of a target molecule associated with a SNP.

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach

the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
March 28, 2006

CARLA J. MYERS
PRIMARY EXAMINER